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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,898	01/18/2002	Wolfgang A. Renner	1700.0190005/BJD/SJE	7794

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EXAMINER	
CAMPELL, BRUCE R	
ART UNIT	PAPER NUMBER
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/19/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/050,898	RENNER ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,24-27,29-36 and 38-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,24-27,29-36 and 38-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/14/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 24-27, 29-36, 38-74 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 220-257, 355-361 of copending Application No. 10/050902. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reason. Although the claims of '902 are not directed specifically to amyloid beta peptide, the allowed copending claims are drawn to a genus of self antigens. Amyloid beta peptide is an obvious species within this genus, because the disclosure supporting the claims of '902 includes a discussion of amyloid beta as an example of self antigen. Therefore, the instant claims are obvious species within the previously allowed genus.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 2, 24-27, 29-35, 50-74 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6-51 of copending Application No. 10/622087. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a genus which embraces the amyloid beta peptide species claimed in the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

These double patenting rejections are not necessitated by applicant's amendment, and therefore this action is nonfinal.

Claim Rejections - 35 USC § 112

Claims 52 and 74 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an immunogenic composition for inhibition or treatment of Alzheimer's amyloidogenesis, does not reasonably provide enablement for a vaccine, treating or preventing Alzheimer's disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Applicant's response, and the cited art, have been carefully considered. Key points, in the examiner's view: the abbreviated human studies used a composition containing a component absent from the immunogens used in animals, which may have contributed

to the unpredicted inflammatory response in humans; autopsy results on participants in the human studies show less amyloid accumulation than expected; there were mixed results on improvement in Alzheimer's symptoms for the human study participants. The review by Janus indicates continuing skepticism in the art regarding the value of mouse models of Alzheimer's disease and the relationship between amyloid deposition and dementia. See for example section 1.3 and section 2.2. However, Janus also cites dramatic evidence of reduction in amyloid in autopsy of an immunized participant in the human trial. This is further substantiated in Masliah et al (Neurology 64:129-131, 2005). Gilman et al provides evidence of some memory improvement, but no improvement in other measures of clinical condition, for the participants showing an antibody response. Considering the post-filing evidence related to substantiating the assertions made in the specification, and the level of skill in the art at filing date, the record as a whole leads to the following conclusion. The teachings of the specification, when combined with the skill of the art at the time of the invention, were sufficient for practice of an immunization method that inhibits or treats Alzheimer's amyloidogenesis, but that prevention or treatment of frank Alzheimer's disease would require undue experimentation.

Response to Amendment and Arguments

Since enablement of only one method of use is required to satisfy the how-to-use component of 112, 1st for a product, the enablement rejection is withdrawn from the remaining claims.

The rejections over prior art are withdrawn in view of the claim amendments and applicant's arguments.

Allowable Subject Matter

Subject to resolution of double patenting issues, claims 1, 2, 24-27, 29-36, 38-51, 53-73 are otherwise allowable.

Election/Restrictions

Subject to resolution of double patenting issues, claims 1, 2, 24-27, 29-36, 38-51, 54-73 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 51, 53, 74, directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on 12/30/2005 is hereby withdrawn**. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906, or to Michelle Horning, whose telephone number is 571-272-9036. The examiner can normally be reached on varying dates and times; please leave a message.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

10/27/06

MARY E. MOSHER, PH.D.
PRIMARY EXAMINER

MARY E. MOSHER, PH.D.
PRIMARY EXAMINER